

## REMARKS

### 1. Status of the Claims

In the office action of October 6, 2004, the Examiner rejected claims 1-54. In this response, applicants have amended claims 1, 53, and 54 and canceled claim 39. The amendments to claims 1, 53, and 54 merely insert commas to make the claims easier to read. Claim 39 was inadvertently omitted from the original application. In this response, applicants have marked claim 39 as "canceled" to make it clear that there is no claim 39 pending in this application. No new matter is added by the amendments.

In applicants' previous response, filed on June 9, 2004, applicants amended the Abstract of this application to change the word "comprises" to "contains" as suggested by the Examiner. However, applicants inadvertently failed to underline the added word "contains." Therefore, applicants have presented the amendment to the Abstract again in this response, with the correct markings, so there will be no confusion regarding the amendment.

After entry of the amendments, claims 1-38 and 40-54 are pending in this application.

### 2. Rejections under 35 U.S.C. § 112

The Examiner rejected claims 1-38 and 40-54 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner contends that "the claims are indefinite and/or incomplete because an azeotrope is normally defined by its pressure and composition, but which parameters are not specified in the claims." (Office action of April 6, 2004, at page 2, incorporated by reference in the office action of October 6, 2004, at page 2.) The Examiner apparently contends that the claims must recite a specific pressure and exact weight percentages for each component of the azeotrope. With all due respect, there is absolutely no legal basis for this contention.

Section 112, second paragraph, requires that the claims, when read in light of the specification, reasonably apprise a person skilled in the art of the scope of the invention. *Utah Medical Products, Inc. v. Graphic Controls Corp.*, 350 F.3d 1376, 69 U.S.P.Q.2d 1136, 1139 (Fed. Cir. 2003). If a person of ordinary skill in the art would understand the claim, then § 112, second paragraph, is satisfied. *In re Oetiker*, 23 U.S.P.Q.2d 1661, 1662 (Fed. Cir. 1991). In this case, the term “azeotrope” has a well-understood meaning in the relevant art. There is absolutely no basis for the Examiner to say that this term is indefinite. Further, the idea that the claim must recite specific weight percentages for each component of the azeotrope and must also recite a specific pressure is absolutely without legal basis.

In further support of the § 112 rejection, the Examiner noted that claim 1 recites “distilling the mixture by a method comprising the steps of (i) heating the mixture sufficiently to product a first vapor stream comprising at least one azeotrope comprising the cyclic ester of the hydroxyl organic acid and the at least one azeotroping agent . . . .” The Examiner apparently contends that the use of the term “distilling” in the claim without also reciting in the claim evaporation, vaporization or boiling, and condensation, renders the claim indefinite. The Examiner argues that the claim as written covers other heating operations, such as evaporation or heat exchange, which are distinct from distillation.

As stated above, under § 112, second paragraph, the claims must reasonably apprise a person skilled in the art of the scope of the invention. If a person of ordinary skill in the art would understand the claim, then the claim meets the requirements of § 112, second paragraph. In this case, “distillation” is a very well-known term which would be easily understood by a

person of ordinary skill in the relevant art. There is no ambiguity or vagueness, and no basis for an indefiniteness rejection.

The Examiner's comments seem to imply a requirement that the claim explicitly recite every feature of each claim element as it would be practiced in the real world. For example, if a distillation operation would typically include condensation of an overhead stream, the Examiner seems to imply that condensation would therefore need to be explicitly recited in the claim in order to satisfy § 112, second paragraph. This is clearly incorrect as a matter of law. There is no support for this in either the statute or the case law. "A claim is not defective when it states fewer than all of the steps that may be performed in practice of an invention." *Smith & Nephew, Inc. v. Ethicon, Inc.*, 276 F.3d 1304, 1311, 61 U.S.P.Q.2d 1065 (Fed. Cir. 2001).

In this case, the key point is that "azeotrope" and "distilling" would be understood by a person skilled in the art. Therefore, the indefiniteness rejections should be withdrawn.

### 3. Rejections for Double Patenting and Obviousness-Type Double Patenting

The Examiner provisionally rejected claims 1-54 for obviousness-type double patenting over claims in co-pending applications 09/809,243 and 09/809,649. The Examiner also provisionally rejected claims 1-54 for double patenting over claims in the same two applications.

A "same invention" double patenting rejection (as opposed to an "obviousness-type" double patenting rejection) is proper only when the two claimed inventions are identical in scope. *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q.2d 2010, 2015 (Fed. Cir. 1993); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619, 621-622 (C.C.P.A. 1970). That is clearly not true in this case. The claims pending in the other two applications contain limitations that are different from those

in the claims in this application. The double patenting rejection is plainly inappropriate and should be withdrawn.

Obviousness-type double patenting "requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent." *In re Berg*, 46 U.S.P.Q.2d 1226, 1229 (Fed. Cir. 1998). In this case, of course, the rejection is based on another patent application, rather than an issued patent. "Generally a 'one-way' test has been applied to determine obviousness-type double patenting. Under that test, the examiner asks whether the application claims are obvious over the patent claims." *Id.* In this case, applicants contend that the three sets of claims are sufficiently distinct in terms of their limitations that there is no obviousness-type double patenting issue. Because the rejection is only provisional at this point, applicants will not comment further on the merits until claims are allowed in one of the three applications.

#### 4. Rejections under 35 U.S.C. § 103

The Examiner rejected claims 1-16, 18-32, 34, and 36-54 as being obvious under 35 U.S.C. § 103(a) in view of Benecke U.S. Patent 5,319,107, alone or in combination with Perry, Chemical Engineers' Handbook (5<sup>th</sup> ed.), pp. 13-36 through 13-42. The Examiner further cited Baniel U.S. Patent 5,510,526 in support of the rejection of claim 17, WO 00/64850 in support of the rejection of claim 33, and Kulprathipanja U.S. Patent 5,068,418 in support of the rejection of claim 35.

The Examiner contends that Benecke discloses the process of claim 1, except that Benecke "does not positively disclose producing a first vapor comprising at least one azeotrope comprising the cyclic ester of the hydroxyl organic acid and the azeotroping agent." (Office action of

April 6, 2004, at page 5, incorporated by reference in the office action of October 6, 2004, at page 3.) The Examiner further contends that it would have been obvious that an azeotrope is formed in the process of Benecke because the reference suggests at column 13, lines 55-68, the process of codistilling cyclic ester with alkylbenzene. The Examiner also cites a passage from page 13-36 of Perry for the proposition that the codistillation of Benecke would inherently form an azeotrope.

The Examiner further relies on Fowlkes U.S. Patent 5,175,639 as proof that codistillation is synonymous with azeotropic distillation, referring in particular to column 1, lines 26-28, where Fowlkes states "In the case of an organic in water azeotrope, one often may add a hydrocarbon as the codistillation agent to aid in the separation."

Applicants respectfully disagree with the § 103(a) rejections. The Examiner has not interpreted the teachings of the references correctly.

Claim 1 of this application requires:

mixing a feed stream and at least one azeotroping agent, thereby producing a mixture, wherein the feed stream comprises at least one of a hydroxy organic acid, an ammonium salt of a hydroxy organic acid, an amide of a hydroxy organic acid, or an ester of a hydroxy organic acid and wherein the at least one azeotroping agent is capable of forming at least one azeotrope comprising a cyclic ester of a hydroxy organic acid; and

distilling the mixture by a method comprising the steps of

(i) heating the mixture sufficiently to produce a first vapor stream comprising at least one azeotrope comprising the cyclic ester of the hydroxy organic acid and the at least one azeotroping agent . . . .

Contrary to the Examiner's assertion, Benecke does not disclose the same process, inherently or otherwise. With reference to Figure 1 of Benecke, a feed stream (2) containing hydroxy carboxylic acid (XA) and a heterogeneous azeotropic solvent stream (8) are fed to a

treatment vessel (6). The treatment vessel is heated to a temperature sufficient to promote formation of the cyclic ester of the hydroxy carboxylic acid. A vaporous azeotrope (16) comprising water and solvent exits the treatment vessel (6) and passes through a condenser (18). Separately, a product stream (32) comprising solvent and cyclic ester exits the treatment vessel (6) and passes into a concentrator (34). (See column 19, line 62 through column 20, line 44.)

Benecke repeatedly describes the solvent-water stream leaving the treatment vessel as an azeotrope. (See column 2, lines 63-65, column 3, lines 36-38, column 10, lines 38-41, and column 11, lines 60-63, for example.) However, in the passage cited by the Examiner regarding the solvent-cyclic ester stream, Benecke never uses the term "azeotrope."

In another embodiment, an aqueous XA feed stream is heated to remove water therefrom until a DP by HPLC of about DP 4 or below is obtained to produce cyclic ester in the solution. The cyclic ester-containing solution is then introduced to a codistillation reaction in which a solvent, such as an alkyl benzene, preferably a C<sub>10</sub>-C<sub>22</sub> alkyl benzene, is vaporized to provide heat transfer for the reaction and for codistillation of cyclic ester.

(Column 13, lines 52-59.) The Examiner argues that "codistillation" in this passage implies or is synonymous with azeotropic distillation, but this flies in the face of the exact language of the Benecke patent. Why would Benecke use the term "azeotrope" to describe the solvent-water stream in his process but use "codistillation" to describe the formation of the solvent-cyclic ester stream rather than "azeotropic distillation"? The unavoidable answer is that Benecke used different terms for the two streams because one was an azeotrope and the other was not.

The Examiner's reliance on Fowlkes cannot overcome the clear teachings of Benecke. Whether or not Fowlkes regarded "azeotrope" and "codistillation" as meaning the same thing in the passage quoted by the Examiner, there is no reasonable way to impute that meaning to

Benecke. Fowlkes' usage of these two terms does not prove an art-recognized convention that the two words are synonyms; at best it shows only Fowlkes' particular usage of those two terms.

What is far more relevant is the way that Benecke himself used the two terms, and as discussed above, Benecke seems to draw a clear distinction between (1) the azeotrope formed in the solvent-water stream and (2) the solvent-cyclic ester stream which he does not describe as an azeotrope.

It becomes even clearer that Benecke does not disclose azeotropic distillation of the cyclic ester when one reviews the examples in the Benecke patent. For example, in Example 35 (column 41, line 40 through column 42, line 58), Benecke describes codistillation of lactic acid and lactide (LD) with an alkyl benzene. "Alkyl benzene and lactide codistill at 165° -177° C at 56 torr." (Column 41, line 68 through column 42, line 1.) This is a wide boiling range and does not indicate an azeotrope.

Applicants also submit for consideration by the Examiner the case of *Dow Chemical Co. v. Sumitomo Chemical Co.*, 257 F.3d 1364, 59 U.S.P.Q.2d 1609 (Fed. Cir. 2001), in which the court construed a claim that contained the phrase "conducting the reaction in the presence of an organic solvent which codistills with water and said epihalohydrin at a boiling point below the boiling point of the lowest boiling compound among the components in the reaction mixture." *Id.*, 59 U.S.P.Q.2d at 1610. In evaluating the codistillate boiling point limitation from the claim, the court stated:

The district court also reasoned that a numerical comparison is required because "clause 1 of claim 1 was developed on the model of a minimum boiling azeotrope." The district court noted that in the grandparent and parent applications of the '255 patent, the phrase "ternary azeotrope" was used instead of the word "codistillate." Although our construction requires a numerical comparison of boiling points, this determination is not based on the fact that the claim language was "developed on the model of" an azeotropic mixture. The fact that the claim

language was changed from “ternary azeotrope” to “codistillate” in the continuation-in-part application suggests that the terms have different meanings. Indeed, Sumitomo’s experts admit that an azeotropic mixture has a “constant composition,” and if the “composition is changing at a defined temperature and pressure, then the composition changing would not be an azeotrope.” Because the compositions involved in the claimed process constantly change during the process, the codistillate disclosed in claim 1 of the ‘255 patent is not an azeotropic mixture.

59 U.S.P.Q.2d at 1615-1616 (emphasis added, citations omitted). In the same way, Benecke’s use of “azeotrope” to describe the solvent-water stream (16 in Fig. 1; see column 19, line 62 through column 20, line 17)) and the term “codistillation” to describe the production of the solvent-cyclic ester stream (see column 13, lines 55-60) indicates that the latter is not an azeotropic distillation.

Considering all the facts, it becomes clear that codistillation and azeotropic distillation are not art-recognized synonyms, and that Benecke does not teach the process of claim 1. Therefore, the Examiner’s rejection of claim 1 cannot stand, whether Benecke is viewed alone or in combination with Perry, Baniel, WO 00/64850, and/or Kulprathipanja. Claims 2-41 depend on claim 1 directly or indirectly, and therefore are nonobvious for the same reasons. Claims 42-54 likewise require formation of azeotropes that are not suggested by the references, and are nonobvious as well.

#### **5. Supplemental Information Disclosure Statement**

Applicants filed a Supplemental Information Disclosure Statement on September 28, 2004, which cited Verser, U.S. Patent No. 5,750,732, and a European Search Report. A copy of Form PTO-1449 is attached to this response. Applicants request that the Examiner initial these references to confirm that they have been considered.



**6. Conclusion**

Applicants believe that claims 1-38 and 40-54 are in condition for allowance. Please call the undersigned attorney if there are any questions regarding this response.

Respectfully submitted,

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November 23, 2004



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